

REMARKS

Claims 1-5, 7, and 11-16 were pending in the application. Claims 7, 11, and 12-13 have been amended and claims 6, 8-10, and 17-30 have been cancelled, without prejudice. Accordingly, after the amendments presented herein have been entered, claims 1-5, 7, and 11-16 will remain pending.

Support for the amendments to the claims can be found throughout the specification and in the claims as originally filed. Specifically, support for claim 11 may be found, at least at, page 8, lines 23-24 and at page 12, lines 28-32 of the specification.

No new matter has been added. Any amendment or cancellation of the claims should in no way be construed as an acquiescence to any of the Examiner's rejections and was done solely to expedite the prosecution of the application. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

Allowed Claims

Applicants gratefully acknowledge the indication by the Examiner that claims 1-5 are allowed.

Oath/Declaration

The Examiner indicates that the oath or declaration is objected to because it lacks the citizenship of the inventors. Applicants enclose herewith a newly executed Declaration, Petition and Power of Attorney document executed by Ajith A. Welihinda and Ronald Kaufman. Mr. Witoon Tirasphon is in Thailand and we have not yet received the executed document from him. Upon receipt, Applicants will forward same to the United States Patent and Trademark Office.

Acknowledgment of the Examiner's Withdrawal of Certain Rejections

Applicants gratefully acknowledge the Examiner's withdrawal of the following: (a) The previous rejection of claims 3-5 and 7 under 35 U.S.C. §101; and (b) The previous rejections of claims 14-16 under 35 U.S.C. § 112, Second Paragraph.

Rejection of Claims 13-15 Under 35 U.S.C. §101

The Examiner has rejected claims 13-15 under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. Although Applicants traverse the foregoing rejection, in an effort to expedite prosecution and in no way conceding the validity of the Examiner's position, Applicants have amended claim 13 to recite "an isolated host cell," as suggested by the Examiner. Applicants therefore respectfully request withdrawal of the rejection under 35 U.S.C. §101.

Rejection of Claims 11-12 and 16 Under 35 U.S.C. §112, First Paragraph

The Examiner has rejected claims 11-12 and 16 under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the Examiner indicates that "[n]o proper antecedent basis nor conception in context with that disclosed within the specification at the time of filing Applicants' invention is apparent from the recitation of 'wherein the fragment comprises at least 10 contiguous amino acid residues of the amino acid sequence of SEQ ID NO:2.' "

Applicants traverse the foregoing rejection, however, in the interest of expediting prosecution and in no way conceding to the Examiner's rejection, Applicants have amended claim 11 to remove the phrase "wherein the fragment comprises at least 10 contiguous amino acid residues of the amino acid sequence of SEQ ID NO:2." Claim 11 has been further amended to recite a "...biologically active fragment of the amino acid sequence of SEQ ID NO:2, wherein the fragment has an activity selected from the group consisting of kinase activity, endoribonuclease activity, and autophosphorylation activity." Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

Rejection of Claims 11-12 and 16 Under 35 U.S.C. §112, First Paragraph

The Examiner has also rejected claims 11-12 and 16 under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that he inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the Examiner indicates that “no recitation of structural features common to the members of the genus, *which features constitute a substantial portion of the genus*’ is recited in the claims” (*Emphasis added*).

Applicants respectfully traverse the foregoing rejection and submit that the instant specification describes the nucleotide sequence of *hIRE1* and the amino acid sequence of *hIRE1p* ***which define and limit the structure of any nucleic acid or polypeptide fragments such that one skilled in the art would be able to immediately envisage members of the genus.*** In addition, Applicants specifically teach that a fragment of the invention refers to a portion of the subject nucleic acid, which may be constructed artificially (*e.g.*, through chemical synthesis) or by cleaving a natural product into a multiplicity of pieces (*e.g.* with a nuclease or endonuclease to obtain restriction fragments) (see page 13, lines 16-22 of the specification). In particular, the instant specification discloses fragments of the protein of the invention that are capable of exhibiting biological activity (see page 8, lines 23-24; page 12, lines 28-32; and page 13, lines 16-22 of the specification), such as kinase activity, endoribonuclease activity and autophosphorylation activity (page 17, line 23 through page 20, line 24 and at page 3, lines 15-17 of the specification), and may be used in, for example, screening assays (page 12, lines 28-32 of the specification). Applicants further teach that the fragments may be in linear form or cyclized and may be fused to carrier molecules using known methods (page 12, lines 28-32 of the specification).

Furthermore, as provided in Example 15 of the *Interim Guidelines*, the generation of fragments is *routine*. For example, (as indicated in Example 15 of the *Interim Guidelines*) any specified fragment can be ordered from a commercial synthesizing service. Thus, based on the teachings in Applicants’ specification, one of skill in the art would conclude that Applicants were in possession of the claimed invention at the time of filing. In view of all of the foregoing,

Applicants respectfully request reconsideration and withdrawal of the rejection of the pending claims under 35 U.S.C. § 112, first paragraph.

Rejection of Claims 11-12 and 16 Under 35 U.S.C. §112, First Paragraph

The Examiner has rejected claims 11-12 and 16 under 35 U.S.C. §112, first paragraph because the specification, while being enabling for an isolated nucleic acid molecule encoding the human hIRE1p polypeptide of SEQ ID NO:2, does not reasonably provide enablement for any structurally and functional undefined hIRE1p polynucleotides, or biologically functional equivalents thereof. According to the Examiner, “the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.” The Examiner is of the opinion that “no distinguishable and assayable functional language is recited in the claims.”

Applicants respectfully traverse the foregoing rejections. However, in the interest of expediting prosecution, and in no way conceding to the validity of the rejection, the instant claims have been amended to remove the term “biological activity” and now specifically recite “kinase activity, endoribonuclease activity, and autophosphorylation activity.” Support for this amendment may be found, at least at, page 17, line 23 through page 20, line 24 and at page 3, lines 15-17 of the specification). In view of the amendments to the claims, the aforementioned rejection has been rendered moot. Accordingly, Applicants respectfully request that the Examiner allow the pending claims.

Rejection of Claims 12 and 16 Under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 12 and 16 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants traverse the foregoing rejection, however, in an effort to expedite prosecution and in no way conceding the validity of the Examiner’s position, Applicants have amended claims 12 and 13, as suggested by the Examiner. Applicants therefore respectfully request withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

Rejection of Claims 7 Under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claim 7 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have amended claim 7 to be dependent upon claim 1. Applicants therefore respectfully request withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

Rejection of Claims 11-12 and 16 Under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 11-12 and 16 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner indicates that “[i]t remains unclear what metes and bounds the recitation ‘having biological activity’ is envisioned to entail.”

Applicants traverse the foregoing rejection. As set forth above, in the interest of expediting prosecution, and in no way conceding to the validity of the rejection, the instant claims have been amended to specifically recite “kinase activity, endoribonuclease activity, and autophosphorylation activity.” Support for this amendment may be found, at least at, page 17, line 23 through page 20, line 24 and at page 3, lines 15-17 of the specification). In view of the amendments to the claims, the aforementioned rejection has been rendered moot. Accordingly, Applicants respectfully request that the Examiner allow the pending claims.

Rejection of Claims 11-12 and 16 Under 35 U.S.C. §102 (b)

The Examiner has rejected claims 11-12 and 16 under 35 U.S.C. §102(b) as being anticipated by Mori *et al.* According to the Examiner, Mori *et al.* teach a polynucleotide encoding an IRE1 protein ‘comprising a fragment of the amino acid of SEQ ID NO:2’ (i.e., residue#s 622-628; pg. 747; Fig. 4), which inherently has immunogenic ‘biological activity.’” Furthermore, the Examiner indicates that Mori *et al.* “teach expression vectors/control sequences...yeast and/or *E. coli* host cells, and a method of recombinantly producing their IRE1 polypeptide.”

Applicants respectfully traverse the rejection. Mori *et al.* discloses the protein, ERN1p, a 1115 amino acid transmembrane protein that contains a protein kinase domain. Mori *et al.* suggest that the accumulation of unfolded protein in the endoplasmic reticulum leads to activation of the cytosolic domain of Ern1p, which is homologous to the catalytic domains of protein kinases belonging to the CDC28/cdc2⁺ family of serine/threonine kinases. However, the sequence disclosed by Mori *et al.* does not have significant overall homology with the instantly claimed polypeptide sequence of SEQ ID NO:2. Specifically, the sequence shown in Figure 4 (Accession No. AAA34489) of Mori *et al.* is merely 25.9% identical to SEQ ID NO: 2. As the Examiner is aware, 35 U.S.C. § 102 requires that in order to anticipate the claimed invention, the prior art reference must teach *each and every element* of the claimed invention. ***Conversely, Mori et al. does not teach or suggest a biologically active protein fragment of SEQ ID NO:2 which has an activity selected from the group consisting of kinase activity, endoribonuclease activity, and autophosphorylation activity, as required by Applicants' claim 11.***

Thus, contrary to the Examiner's assertion, the Mori *et al.* reference fails to teach or suggest the subject matter of the pending claims. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection.

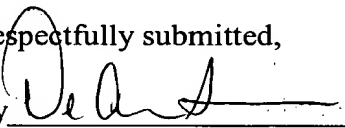
SUMMARY

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 12-0080, under Order No. UMV-1584 from which the undersigned is authorized to draw.

Dated: March 11, 2004

Respectfully submitted,

By 

DeAnn F. Smith

Registration No.: 36,683

LAHIVE & COCKFIELD, LLP

28 State Street

Boston, Massachusetts 02109

(617) 227-7400

(617) 742-4214 (Fax)

Attorney/Agent For Applicant